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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,022	05/04/2001	Joseph D. Gold	091/005P	7806

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GERON CORPORATION
230 CONSTITUTION DRIVE
MENLO PARK, CA 94025

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/849,022	**Applicant(s)** GOLD ET AL.	
	Examiner Thaian N. Ton	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *08 November 2004*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-3,6,8,9 and 13-36*.

   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Joe Woitach

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Continuation of 11. does NOT place the application in condition for allowance because: The amendments to the claims and Applicants' arguments have been considered but are not found persuasive. The prior rejections of record are maintained. Because no terminal disclaimer has been filed, the prior rejection, for obviousness-type double patenting, over claims 62-63 of US Application. No. 09/530,346 (now U.S. Pat. No. 6,800,480) is maintained for reasons of record. Applicants argue that the '480 patent does not explicitly claim genetically altered cells cultured on an extracellular matrix, in a medium cultured by fibroblast feeder cells. Further, Applicants argue that there are other ways of producing genetically altered pPS cells, and provide several methods. See p. 7 of the Response. This is not persuasive. Firstly, the instant claims, which are directed to both products and methods of making those products, are obvious over the products of the '480 claims, because the '480 cells encompass cells that are cultured on an extracellular matrix and cultured in a medium cultured by fibroblast feeder cells. Furthermore, the instant product claims (see claim 8, for example) fail to differentiate from the '480 claims, as there is no recitation of extracellular matrix or medium cultured by fibroblast feeder cells. Thus, instant claims are rendered obvious because they are broader than the '480 claims. Finally, specific review of the '480 prosecution history shows that the methods disclosed indicate that a conditioned medium is used to culture the cells. Thus, it is maintained that the instant claims are rendered obvious over claims 10-11 of the '480 patent.

The 112, 1st rejection, for enablement, is maintained for claims 8, 9, 13, 15,16, 18, 19, 25-36 is maintained for reasons of record. The rejection of the method claims (1-3, 6, 17,20-24) is withdrawn in view of Applicants' amendment, reciting that the medium is conditioned by fibroblast feeder cells. Applicants argue that the prior rejection should be withdrawn for all of the claims because, as amended, the rejection is overcome. See pp. 6-7 of the Response. The claims that are maintained in this rejection do not recite that they are cultured on an extracellular matrix and in the presence of media conditioned by fibroblast feeder cells. Thus, the prior rejection of record is maintained, that the specification fails to provide any teachings or guidance for culturing hES cells in a culture environment without fibroblast conditioned medium, without an extracellular matrix. The claims require that the cells remain undifferentiated after transfection. The specification provides no teachings/guidance with regard to specific conditions such that hES cells would remain undifferentiated after transfection except when cultured on an extracellular matrix and in the presence of fibroblast-conditioned medium.